NIHON KOHDEN AMERICA, INC.
June 19, 2001

510(k) NOTIFICATION
BSM-2300A Series Bedside Monitor

SEP 1 2 2001

SECTION 2 - 510(K) SUMMARY

Name and Address of Applicant
Nihon Kohden America, Inc.
Contact: Regulatory Affairs Manager
90 Icon Street
Foothill Ranch, CA 92610

Phone: (949) 580-1555
Fax: (949) 580-1550

Device Name: BSM-2300A Series Bedside Monitor. Common names for the device include Bedside Monitor, Patient Monitor, Transport Monitor, Cardiac Monitor and Vital Signs Monitor. The classification name for the device is Physiological Patient Monitor with Arrhytmia Detection and Alarms

Legally Marketed Predicate: Nihon Kohden BMS-4100A Series Bedside Monitor per 510(k)# K001693.

Description and Intended Use: The device is a multi-parameter monitor consisting of a color LCD touch-screen to display waveforms and numerics of monitored parameters, multi-parameter input unit (socket panel), visual alarm indicator and a removable battery pack. Options include a built-in thermal array recorder and network communications card. The device is software driven. Both the device and the predicate have the same intended use to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to monitor the electrocardiogram and generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2) noninvasive blood pressure (NIBP) invasive blood pressure (IBP), body temperature, CO_2 and $EtCO_2$, and respiratory rate. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. This device may also condition and transmit physiological signals via radio frequency. This device will be available for use by medical personnel on all patient populations.

Performance Testing

- The device complies with IEC 601-1 subclause 56.3(c) implemented by 21 CFR Part 898 Performance Standard for Electrode Lead Wires and Patient Cables. To date, no other special controls or performance standards are known or established for this device. The device is designed to comply with the following voluntary industrial standards: IEC 60601-1 (1988-12), Amendment 1 (1991-11), Amendment 2 (1995-03), IEC 60601-1-1 (1992-06), IEC 60601-1-2 (1993-05), CISPR11 Group 1, Class B, IEC 60601-2-27 (1994), IEC 60601-2-30 (1995-03), IEC 60601-2-34 (1994-12)

- The device is not sterile.

- The device does not directly contact patients. Accessories that contact patients, such as probes and thermistors, are the same accessories as used with other legally marketed products or are comprised of the same component materials as the predicate accessories except as noted below. The disposable SpO2 probes include No.1776 3M Nonwoven Medical Tape which may contact the surface of intact skin. According to the manufacturer, 3M, the material was tested in accordance with ISO 10993 and Good Laboratory Practices with results characteristic of adhesive materials within historically acceptable levels.

- The device was subjected to environmental testing including temperature/humidity stress testing, electromagnetic interference / electromagnetic compatibility testing and safety standards testing and performance testing procedures. Test criteria is established prior to testing based upon product specifications and applicable standards. The completed testing showed that the device met its product specifications and verified conformance to safety, reliability, and applicable standards. Software verification and validation tested the operation of the software functions of the device. The results confirmed that the device performed within specifications.

There are no significant changes in function, biocompatibility, performance or manufacturability compared to the predicate device that would affect the safety and effectiveness of the device as intended for use. Therefore, Nihon Kohden believes that the new BSM-2300 Series, is substantially equivalent to the predicate BSM-4100A Series Bedside Monitor.

SECTION 3 - PROPOSED LABELING

A. Intended Use

The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to monitor the electrocardiogram and generate visible and/or audible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2) noninvasive blood pressure (NIBP) invasive blood pressure (IBP), body temperature, carbon dioxide concentration (CO_2 and $EtCO_2$), and respiratory rate. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits.

B. Device/Package Labels

The proposed product labels for the device are located in Attachment 2.

C. Proposed Packaging

Packaging for the device is depicted in Attachment 3.

D. Instructions for Use

The proposed instructions for use are provided with each packaged device and are presented in Attachment 9.

E. Advertisement/Promotional Literature

To date no advertisement or promotional literature for this device has been created for distribution in the United States.

F. Contraindications, Precautions & Warnings

Warnings and cautions are listed in the Operator's Manual as shown in Attachment 4.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2001

Ms. Bonnie Bishop
Nihon Kohden America, Inc.
90 Icon Street
Foothill Ranch, CA 92610

Re: K011918
Trade Name: Nihon Kohden BSM-2300A Series Bedside Monitor and Accessories
Regulation Number: 21 CFR 870.1025
Regulatory Class: III (three)
Product Code: MHX
Dated: June 19, 2001
Received: June 20, 2001

Dear Ms. Bishop:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

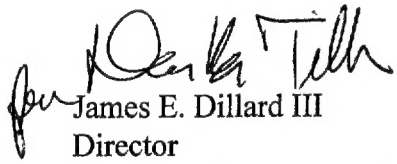
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

G. Indications for Use Statement

510(k) Number (if known): K011918

Device Name: BSM-2300A Series Bedside Monitors

Indications for Use:

The device is intended to monitor, display and record physiological data to provide cardiac and vital signs monitoring within a medical facility. The device is intended to monitor the electrocardiogram to generate audible and/or visible alarms when an arrhythmia exists. The device is also intended to monitor heart rate, pulse rate, blood oxygen saturation (SpO_2) noninvasive blood pressure (NIBP) invasive blood pressure (IBP), body temperature, carbon dioxide concentration (CO_2 and $EtCO_2$), and respiratory rate. The device may generate an audible and/or visual alarm when a measured rate falls outside preset limits. The device may also condition and transmit physiological signals via radio frequency. The device will be available for use by medical personnel on all patient populations.

Division of Cardiovascular & Respiratory Devices
510(k) Number K011918

Prescription Use ✓
(Per 21 CFR 801.109)